

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Matthias Ebert et al.  
Serial No. : 10/575,300 Group Art Unit: 1642  
Filed : September 18, 2006 Examiner: Sean E. Aeder  
For : MN/CA IX and Cancer Prognosis

AMENDMENT

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Amendment concerning the above-identified application is in response to the Office Action mailed from the U.S. Patent and Trademark Office (PTO) on June 20, 2008. Preliminary to further examination of the above-identified application, please amend the claims as indicated below.

Also, the following is a Statement of Substance of a telephone interview conducted between Examiner Sean Aeder and Attorney and Agent for Applicants on September 10, 2008, concerning the above-identified application.

STATEMENT OF SUBSTANCE  
OF SEPTEMBER 10 INTERVIEW

Applicants would like to thank Examiner Aeder for granting a telephone interview on Wednesday, September 10 at 2PM (EDT) to the Attorney for the Applicants, Leona Lauder, and the undersigned Agent for the Applicants, Joan Harland, Ph.D. During that interview, Applicants discussed the proposed claim amendments that had been faxed to the Examiner by the Applicants, and how the amendments address the points in the remaining 35 USC §112, ¶1 enablement rejection.

Applicants stated that they thought that the proposed claim amendments answered the points in the Office Action regarding the remaining 35 USC §112, ¶1 enablement rejection, as the claimed methods were now directed to the subject disease (gastric cancer) and type of prognosis (shorter survival) that had been indicated as allowable in the Examiner's previous office actions. The Applicants pointed out that although no working examples are required for enablement, the instant specification provides working examples that support the claims, particularly working examples using MN/CA IX levels from gastric preneoplastic/neoplastic tissue samples and comparable samples, to predict a prognosis of shorter survival in gastric cancer patients. Those working examples directly support the claims as amended.

The Examiner stated that, he thought that the draft claim amendments appeared to resolve the issues he had about the claimed methods. However, he thought that it needed to be clarified that the gastric preneoplastic/neoplastic tissue samples to be tested in the claimed methods "comprised neoplastic cells." Applicants agreed to amend the claims accordingly.

The Examiner then raised a new issue (that is, that had not been raised in the subject prosecution before), questioning the use of the term "preneoplastic /neoplastic disease" in the claims. Applicants respectfully but forcefully countered that the claims would be unduly limited by a requirement that the tissue samples be purely "neoplastic." Applicants respectfully explained that the MN/CA9 is considered to be an oncogene and that the term "preneoplastic/neoplastic" reflects the dynamic nature of the oncogenic process.

At any particular time point during the oncogenic process, one of skill in the art would not consider the cells of a tissue to be purely preneoplastic or purely neoplastic. Applicants respectfully indicated that there is no sharp border demarcating when a preneoplastic cell becomes a neoplastic cell.

Applicants respectfully maintained that the term “preneoplastic/neoplastic” is used to reflect the conventional art knowledge that most cancers are a mixture of preneoplastic cells and neoplastic cells, as cells in a diseased tissue are not synchronized as they undergo carcinogenic progression. Applicants respectfully pointed out that the use of the term “preneoplastic/neoplastic disease” is used in many of the granted claims in commonly-owned patents relating to the MN/CA9 oncogene. [See, for example, the claims of US Patent Nos. 6,027,887; US 6,297,051; US 6,770,438; and US 7,186,514.]

#### Conclusion of Interview

The Examiner said that he would review the claim amendments submitted with the response and determine whether there were any unresolved claim issues. Applicants respectfully point out that the instant claim amendments are essentially the same as those faxed to the Examiner for the September 10 interview, except that the independent claims 1 and 24 have been amended, as discussed in the interview, to indicate that the “gastric preneoplastic/neoplastic tissue sample(s)” comprise neoplastic cells. Also, the term “neoplastic” has been deleted from claims 7 and 10 for clarity and particularity, in accordance with the antecedent in claim 1, (that is, “gastric preneoplastic/neoplastic disease”), and in view of the above explanations concerning the oncogenic process.